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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/762,893	02/13/01	SCHINDLER U	02481.1734

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EXAMINER	
FORD, J	
ART UNIT	**PAPER NUMBER**
1624	4

DATE MAILED: 07/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/760,993	Schindler et al
Examiner	**Group Art Unit**
TM Ford	1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1 - - 19 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 - - 19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Exhibit A

Office Action Summary

The claims in the application are claims 1--19.

Claims 1--12 were examined by the International Bureau. 37 CFR 1.496(b) prohibit the addition of more claims, as the examiner in the national county would not have the benefit of the examination in the PCT.

Claims 9, 11, 12, 16, 18 and 19 violate 35 U.S.C. 101 ad 35 U.S.C. 112, since they are drafted in terms of use. See Clinical Products vs. Brenner, 255 F. Supp. 151; 149 USPQ 475 (D.C. District Columbia 1966).

Claims 9--12 and 16--19 are not in U.S. claim form.

Line 1 of claim 10 and claim 17 should begin: A pharmaceutical composition comprising one or more --.

Claims 9 and 16 should be cancelled, as applicants cannot support all pharmaceutical uses.

Claims 11 and 18 should be cancelled, as activation of soluble guanylate cyclase does not qualify as a real World Utility. Screen tests or Laboratory tests are not accepted as real World Utilities.

See Exhibit A, page 298, col. 2.

The is a 371 application.

Restriction in 371 applications is controlled by 37 CFR 1.475. 37 CFR 1.475 makes it clear that, in addition to the compound, applicants are entitled to have <u>one</u> clear, understandable utility examined with the compound.

Claims 9--12 and 16--19 are directed to more than one utility. Claims 9-12 and 16-19 should be re-written or canceled so that one understandable method of use, in currently available form is claimed here.

The recent utility guidelines set by PTO require applicants to meet the requirements as stated in Brenner v. Manson in 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available form. Similar is the immediate benefit to the public" standard that Nelson, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 235 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practical employment". This language is echoed in Bindra vs. Kelly 206 USPQ 570. Claim 9 does not meet that test.

37 CFR 1.475 provides for one method of use to be examined with the elected compounds. A broad disclosure of utility as in the cited claims 11 and 18 cannot be deemed in compliance with 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph.

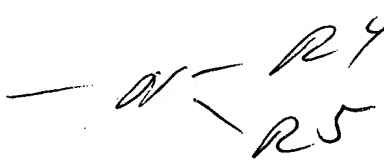
Applicants should pick one use from claims 12 and 19. The claim should be written as a method of treating claims, pick one understandable utility is currently available form. Like, treating high blood pressure.

Claim 15 is rejected under 35 U.S.C. 112, 2nd paragraph. The claim does not indicate what "activating" means.

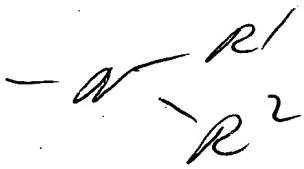
Claims 13 and 14 are rejected under 35 U.S.C. 112, 1st and 2nd paragraph. Mixtures in all ratios are not supportable, Man-made mixture are not in class 544 with the pyrmidine, but in

class 252. Clarification is requested. All mixture in all ratios, made by any means cannot be accepted here. Claims 1-7, and 13, 14 are rejected under 35 USC 112, 1st and 2nd paragraphs.

Claim 1 is rejected under 35 USC 103, as being unpatentable over EP 555,478. Note A in '478 is phenyl as R^3 here. B in '478 is methyl, while here it is the next adjacent, obvious therefrom, ethyl for R^4. R^4 here is also trifluoromethyl and phenyl, as B is in '478. R^3 in '478 is



corresponding to



, here.

Claims 8 and 15 are rejected as being dependent on a rejected claim.

JOHN M. FORD
PRIMARY EXAMINER
GROUP 1624 - ART UNIT 1624

Ford/LR

July 19, 2001